



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of Exclusive Patent License: Development and commercialization of adeno-virus based cancer immunotherapy.

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following Patents and Patent Applications to Etubics Corporation (“Etubics”) located in San Francisco, California, USA:

**Intellectual Property**

United States Provisional Patent Application No.60/904,236 filed February 28, 2007, titled “Brachyury Polypeptides and Methods of Use” [**HHS** Reference No. E-074-2007/0-US-01];

International Patent Application No. PCT/US2008/055185 filed February 28, 2008 titled “Brachyury Polypeptides and Methods of Use” [**HHS** Reference No. E-074-2007/0-PCT-02]; National Stage Applications and issued patents, in the US, EP, CA, AU, JP, HK, and all continuations applications, divisional applications and foreign counterpart applications and patents claiming priority to the provisional application no. 60/904, 236,

United States Provisional Patent Application No. 61/701,525, filed September 14, 2014, titled “Brachyury Protein, Non-Poxvirus Non-Yeast Vectors Encoding Brachyury Protein, And Their Use” [**HHS** Reference No. E-055-2011/0-US-01];

International Patent Application No. PCT/US2013/0059737 filed September 13, 2012 titled “Brachyury Protein, Non-Poxvirus Non-Yeast Vectors Encoding Brachyury Protein, and Their Use” [**HHS** Reference No. E-055-2011/0-PCT-02]; National Stage Applications and issued patents, in the US, EP and all continuations applications, divisional applications and foreign counterpart applications and patents claiming priority to the provisional application no. 60/701,525.

U.S. Provisional Application No. 62/200,438 filed August 3, 2015 titled “Brachyury Deletion Mutants, Non-Yeast Vectors Encoding Brachyury Deletion Mutants, and Their Use” [**HHS** Reference No. E-244-2015/0-US-01] and continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 62/200,438.

US Patent Application No. 61/582,723 filed January 3, 2012 entitled “Native and Agonist CTL Epitopes of The MUC-1 Tumor Antigen” [**HHS** Reference No. E-001-2012/0-US-01] as well as all continuation and divisional applications and foreign issued patents and patent applications claiming priority to the US provisional application no. 61/582,723.

US Patent Application No. 61/894,482 filed October 23, 2013 entitled “Identification and Characterization of HLA-A24 Agonist Epitopes of MUC1-Oncoprotein” [**HHS** Reference No. E-520-2013/0-US-01] as well as all continuation and divisional applications and foreign issued patents and patent applications claiming priority to the US provisional application no. 61/894,482.

U.S. Patent No. 6,756,038 issued June, 29 2004 as well as issued and pending foreign counterparts [**HHS** Ref. No. E-099-1996/0-US-07];

U.S. Patent No. 7,723,096 issued May 25, 2010 as well as continuation and divisional applications, and issued and pending foreign counterparts [**HHS** Ref. No. E-099-1996/0-US-08];

Europe Patent No. 1017810 (**HHS** Ref. No. E-099-1996/0-EP-05, and all European contracting states in which this patent is validated, including: German Patent No. 69824023.5 (**HHS** Ref. No. E-099-1996/0-DE-09); France Patent No. 1017810 (**HHS** Ref. No. E-099-1996/0-FR-10); Great Britain Patent No. 1017810 (**HHS** Ref. No. E-099-1996/0-GB-11); Italy Patent No. 1017810 (**HHS** Ref. No.

E-099-1996/0-IT-12); Spain Patent No. 2217585) (**HHS** Ref. No. E-099-1996/0-ES-13); Switzerland Patent Application No. 98948429.0 (now Switzerland Patent No. 1017810) (**HHS** Ref. No. E-099-1996/0-CH-14); Belgium Patent Application No. 98948429.0 (now Belgium Patent No. 1017810) (**HHS** Ref. No. E-099-1996/0-BE-15); Ireland Patent Application No. 98948429.0 (now Ireland Patent No. 1017810) (**HHS** Ref. No. E-099-1996/0-IE-16); and all continuations and divisional applications claiming priority to any of the above;

Europe Patent Application No. 04011673.3 (now EP Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-EP-17), and all European contracting states in which this patent is validated, including: Austria Patent Application No. 04011673.3 (now Austria Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-AT-28); Belgium Patent Application No. 04011673.3 (now Belgium Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-BE-29); Cyprus Patent Application No. 04011673.3 (now Cyprus Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-CY-31); Denmark Patent Application No. 04011673.3 (now Denmark Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-DK-41); Finland Patent Application No. 04011673.3 (now Finland Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-FI-33); France Patent Application No. 04011673.3 (now France Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-FR-42); Germany Patent Application No. 04011673.3 (now Germany Patent No. 69837896) (**HHS** Ref. No. E-099-1996/0-DE-40); Great Britain Patent Application No. 04011673.3 (now Great Britain Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-GB-43); Greece Patent Application No. 04011673.3 (now

Greece Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-GR-34); Ireland Patent Application No. 04011673.3 (now Ireland Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-IE-35); Italy Patent Application No. 04011673.3 (now Italy Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-IT-36); Luxembourg Patent Application No. 04011673.3 (now Luxembourg Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-LU-44); Monaco Patent Application No. 04011673.3 (now Monaco Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-MC-45); Netherlands Patent Application No. 04011673.3 (now Netherlands Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-NL-46); Portugal Patent Application No. 04011673.3 (now Portugal Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-PT-37); Spain Patent Application No. 04011673.3 (now Spain Patent No. 2286530) (**HHS** Ref. No. E-099-1996/0-ES-32); Sweden Patent Application No. 04011673.3 (now Sweden Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-SE-38); Switzerland Patent Application No. 04011673.3 (now Switzerland Patent No. 1447414) (**HHS** Ref. No. E-099-1996/0-CH-30); and all continuations and divisional applications claiming priority to any of the above;

Japan Patent Application No. 2000-516030 (now JP Patent No. 4291508) (**HHS** Ref. No. E-099-1996/0-JP-06), and all continuations and divisional applications claiming priority to this application;

Australia Patent No. 745863 (**HHS** Ref. No. E-099-1996/0-AU-03), and all continuations and divisional applications claiming priority to this application;

Canada Patent No. 2308127 (**HHS** Ref. No. E-099-1996/0-CA-04), and all continuations and divisional applications claiming priority to this application;

U.S. Patent Application No. 10/579,025 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [**HHS** Ref. No. E-087-2005/0-US-03];

U.S. Patent Application No. 10/579,007 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [**HHS** Ref. No. E-088-2005/0-US-03];

U.S. Patent No. 7,118,738 issued October 10, 2006 as well as all continuations and divisional applications, and issued and pending foreign counterparts [**HHS** Ref. No. E-154-1998/0-US-07];

U.S. Patent Application Nos. 08/686,280 filed July 25, 1996 as well as all issued and pending foreign counterparts [**HHS** Ref. No. E-259-1994/3-US-01];

U.S. Patent No. 7,410,644 issued August 12, 2008 as well as all continuation and divisional applications, and issued and pending foreign counterparts [**HHS** Ref. No. E-259-1994/3-US-08];

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “The development and commercialization of a therapeutic cancer vaccine specifically using Adeno-viral vectors.” For avoidance of doubt, the field of use specifically excludes other viral vectors including but not limited to pox virus vectors, yeast based vectors and other adjuvants and vectors that are not adeno-viral vectors.

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504E-mail: chatterjeesa@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:** This invention concerns Brachyury, a master transcription factor that governs the epithelial-mesenchymal transition, was shown to be significantly overexpressed in primary and metastasizing tumors relative to normal human tissues. Stimulation of T cells with the Brachyury peptide promoted a robust

immune response and the targeted lysis of invasive tumor cells. Brachyury overexpression has been demonstrated in a range of human tumors (breast, lung, colon and prostate, among others) suggesting that an immunotherapeutic product derived from this technology would be broadly applicable for the treatment of cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: May 13, 2016.

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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